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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,389	07/01/2002	Arthur Schaffer	6727/OK318USO	3278

7590 06/09/2004

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EXAMINER	
ROBINSON, KEITH O NEAL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,389	SCHAFFER, ARTHUR	
	Examiner	Art Unit	
	Keith O. Robinson	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 and 6-16 are broadly drawn to a method for breeding tomato plants that produce tomatoes with reduced fruit water content, comprised of crossing *Lycopersicon esculentum* with any other *Lycopersicon* species. Claims 1-16 are also broadly drawn to selecting for any reduction in water content or any degree of skin wrinkling for any duration. Claims 6-7 are broadly drawn to selecting for any increase in dry weight percentage.

In contrast, the specification only provides guidance for crossing a single *Lycopersicon* species, namely *L. hirsutum*, with *L. esculentum* for the introgression of a reduced fruit water content trait. It appears that reduced water content is correlated with or identical to increased soluble solids content, as

taught on page 3 of the specification, lines 8-12 and 17-19; page 6, lines 24-25; page 7, lines 6-8; page 8, lines 31-33; and page 9, lines 1-3. No guidance is provided for the identification of any other *Lycopersicon* species which could confer reduced water content (or increased soluble solids content) to *L. esculentum*. In addition, no guidance is provided for the exact measurement of increased water content, increased dry weight percentage, or increased wrinkling.

Tomato breeding for reduced water content or increased soluble solids content is unpredictable and species-dependent. Davies (Nature. 209: 640-641, 1966) teaches different *Lycopersicon* species have different sucrose concentrations (see, page 641, column 1, table 1 and bottom 3 paragraphs). Since sugar is correlated with soluble solids, different types of sugar and sugar concentration in different *Lycopersicon* species imply that there are different mechanisms of soluble solid accumulation in these different species. *Lycopersicon hirsutum* has very high sucrose levels while the other species, *L. pimpinellifolium* and *L. esculentum*, had lower sucrose levels. The high soluble solids reported in the instant application may be due to the fact that *L. hirsutum* was used as parent in which case, any *L. hirsutum* plant would give higher soluble solids when compared with *L. esculentum* and therefore, only *L. hirsutum* can be crossed with any *L. esculentum* plant to produce progeny with increased soluble solids. Azanza et al. (Theor. Appl. Genet. 87: 965-972, 1994) teach that portions of the genome of another *Lycopersicon* species, *L. chmielewskii,* which

may confer increased soluble solids, can also confer undesirable properties including decreased yield and increased (see, pages 970-972).

In addition, environmental, seasonal, and nutritional variation highly influences tomato fruit water content (see, e.g., Davies et al. (CRC Critical Reviews in Food Science and Nutrition. 15 (3): 205-227, 1981), page 217, bottom paragraph). Thus, in the absence of clear selection criteria as set forth above, it would be unclear whether any variation in fruit water content or skin wrinkling were due to genotypic effects or environmental effects.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify a multitude of non-exemplified wild *Lycopersicon* species which could confer reduced water content or increased soluble solids content to cultivated tomato, or to evaluate the ability of any *Lycopersicon* species to confer reduced water content or increased soluble solids content given the imprecise selection criteria set forth in the specification.

Claims 15 and 16 are rejected as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims appear to employ novel plants characterized by fruit with the capability to dehydrate naturally on the plant and by an untreated skin which permits dehydration of the fruit so as to obtain wrinkling of the skin, respectively. Since the plant is essential to the claimed inventions it must be obtainable by a

repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by at statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807)l and,

(e) the deposit will be replaced if it should ever become inviable.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for breeding a tomato plant comprising crossing *Lycopersicon esculentum* with any other *Lycopersicon* species, and the plants produced by the method. In contrast, the specification only describes interspecific tomato hybrids with *Lycopersicon esculentum* as the recurrent and *Lycopersicon hirsutum* as the donor parent. No other wild *Lycopersicon* species was characterized in the specification regarding its genomic content, its exhibition of the reduced water content trait, or its use as a breeding parent. Furthermore, no progeny containing a genomic introgression from other wild *Lycopersicon* species were described, either in terms of their genomic composition or their exhibition of the reduced water content trait.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of , is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of wild *Lycopersicon* species or their genetic composition,

or the genetic composition of interspecific hybrids derived therefrom, as broadly claimed. Given the lack of written description of the claimed genus of wild *Lycopersicon* species, any method of using them, such as crossing them with *Lycopersicon esculentum*, and the resultant products including the claimed interspecific tomato plants containing the genus of wild *Lycopersicon* sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to a "desired characteristic" that is not defined in the claims or the specification. Thus, one skilled in the art would not know which characteristics are intended, or which plants having which characteristics are intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Eshed and Zamir (Theor. Appl. Genet. 88: 891-897, 1994).

The claims are broadly drawn to any tomato plant which produces fruit with natural dehydration capacity, which is defined as skin wrinkling while remaining on the plant after normal harvest stage, wherein said natural dehydration capacity is correlated with increased soluble solids content, which is correlated with increased resistance to microbial spoilage (see, e.g. page 3 of the specification, lines 17-19).

Eshed and Zamir teach the introgression of alleles from the wild species *Lycopersicon pennellii* into *Lycopersicon esculentum* to improve the soluble solid concentration of cultivated tomato varieties (see, e.g. pages 892-894). The tomato fruit with increased soluble solids taught by Eshed and Zamir would

inherently possess reduced water content and increased tolerance to microbial spoilage, as stated above.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al. (Theor. Appl. Genet. 92: 213-224, 1996). Tanksley et al. teach the introgression of alleles from wild species *L. pimpinelifolium* into cultivated tomato using a backcrossing method for soluble solid concentration improvement (see, e.g. page 214 and 216-219). The tomato fruit with increased soluble solids taught by Tanksley et al. would inherently posses reduced water content and increased tolerance to microbial spoilage, as stated above.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Azanza et al. (Theor. Appl. Genet. 91: 495-504, 1995). Azanza et al. teach introgression of chromosomal segments from the wild species *Lycopersicon chmielewskii* into *Lycopersicon esculentum* and that said introgression reduces fruit water uptake during ripening as well as increases pH, sugars, and soluble solids concentration (see, Table 1, pages 498-499). In addition, they teach tomatoes with the introgression of the wild species, *Lycopersicon chmielewskii*, having higher soluble solid concentrations than the cultivated tomato when ripened on the vine (see, page 500, column 1, first paragraph).

Claims 1-14 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method for selecting tomato plants which produce fruit with reduced water capacity, said selection method comprising allowing the fruit to remain on the plant past normal harvesting, until skin wrinkling is observed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 8 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 8, 2004
KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638